REMARKS

I. Formal Matters

Claims 40-52, 91 and 93-95 are pending and under consideration on the merits. Claims 1-39, 53-90 and 92 stand cancelled without prejudice against their reintroduction into this or any subsequent divisional or continuing applications.

Claims 40, 46 and 91 are amended to indicate that the sample is an un-treated whole blood sample. This is supported in the Abstract, which states: "No sample pre-treatment is required." Claim 40 is also amended for clarity to indicate that the eluting agent flows downstream along the membrane and is allowed to "contact the untreated whole blood sample."

New claim 93 finds support throughout the specification, such as, for example, at page 15, lines 11-13. New claims 94-95 find support throughout the specification, such as, for example, in the Abstract.

The various rejections raised in the Office Action are discussed in more detail below. As no new matter is added by way of these amendments, their entry by the Examiner is respectfully requested.

II. Rejection Under 35 U.S.C. § 103(a)

Claims 40-53 and 91 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Law et al. (U.S. 6,562,581 hereinafter "Law") in view of Ullman et al. (U.S. 4,857,453 hereinafter "Ullman") and U.S. 6,534,324 (hereinafter "Zin").

A determination of obviousness is informed by an analysis of several factors: (1) the scope and content of the prior art; (2) the differences between the claimed invention and prior art; (3) the level ordinary skill in the art; and (4) any relevant secondary considerations (*Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

"Subsumed within the Graham factors is a subsidiary requirement articulated by this court that where, as here, **all claim limitations are found in a number of prior art references**, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to

achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) (emphasis added).

Here, the cited references fail to teach all the claim limitations. Claim 40 has been amended to indicate that an untreated whole blood sample is applied to the receiving portion of the membrane. Law teaches that the separation of glycated hemoglobin from a blood sample is carried out by first diluting and lysing the sample with a buffer containing a lysing agent (col. 2; lines 59-64). In Example 5, the authors state that a whole blood sample is deposited into a sample well. Then, a pump which automates the fluid handling "will measure a predetermined volume of the whole blood sample and dilute it with a lysing agent and a buffer. The mixture is [then] transported into the capture zone" (col. 8, lines 23-26).

In contrast, claim 40 specifies that an untreated whole blood sample is applied directly to the receiving portion of the membrane. The specification teaches that "[a] small sample of fresh whole blood, in a volume on the order of about 2 to about 3 microliters, was then applied to the treated sample application zone of each test strip. The application of the fresh blood sample to each of the test strips resulted in the hemolysis of the blood sample..." No pre-treatment of the sample, such as dilution, is involved.

Zin and Ullman are cited for their alleged disclosures of devices with a membrane comprising an elution area, a sample addition area, a lysing area and a capture area. Neither reference discloses applying a whole blood sample to the receiving portion of a membrane without pre-treatment of the whole blood sample. Accordingly, they do not remedy the deficiencies of Law.

Applicant submits that the claimed invention patentably defines over the prior art, and respectfully requests withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

The pending claims are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided below.

No fees beyond those submitted herewith are believed to be due in connection with this communication. However, the Director is authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ADCI-010.

Respectfully submitted,
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